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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,746	04/27/2006	Arata Toshimitsu	KUZ0030US.NP	2861

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT	PAPER NUMBER
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1609

MAIL DATE	DELIVERY MODE
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06/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,746

Applicant(s)

TOSHIMITSU ET AL.

Examiner

GiGi Huang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/27/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. Claims 1-12 are present for examination at this time.

Information Disclosure Statement

2. The information disclosure statement filed 4/26/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no translation of the prior art listed: JP 2000-514053, JP 2002-515424, JP 11-507361. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

3. The following items of the IDS, only the abstracts were considered as being the only part translated: WO 03/013611 A1, WO 02/069942 A1, WO 03/013613 A1, WO 98/00142, WO 99/59558, JP 2004-083523, JP 2004-083520, WO 99/59558.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claim 9 and dependent claim 10 recites the limitation "(meth)acrylic copolymer" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

The claim is drawn to a (meth)acrylic copolymer in an adhesive layer in claim 1. There is no basis for this claim as claim 1 draws to a transdermal composition containing pergolide with no reference to a polymer, or more specifically a (meth)acrylic copolymer. Thereby there is no basis for the claims.

6. Claim 9 and dependent claim 10 recites the limitation "adhesive layer" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

The claim is drawn to a (meth)acrylic copolymer in an adhesive layer in claim 1. There is no basis for this claim as claim 1 draws to a transdermal composition containing pergolide with no reference to an adhesive layer. A transdermal composition can be many vehicles including a gel, cream, or a patch. An adhesive layer is typically associated with a patch/plaster, but claim 1 is not drawn to that particular vehicle thereby there is no basis for claim 9.

7. Claim 10 recites the limitation "acrylic polymer" in claim 9. There is insufficient antecedent basis for this limitation in the claim.

The claim is drawn to an acrylic polymer in claim 9. There is no basis for this claim as claim 1 draws to a transdermal composition containing pergolide and a (meth)acrylic copolymer. There is no reference to an acrylic polymer, and more specifically claim 10 attempts to exclude the (meth)acrylic copolymer it is dependent on. Thereby there is no basis for the claim.

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8. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim draws to a (meth)acrylic copolymer, which is an acrylic polymer, but then attempts to exclude the (meth)acrylic copolymer it is dependent on. This makes the claim indefinite as to what it is claiming, is unclear what the invention is, and leaves the metes and bounds of the claim unclear. Thereby the claim is rejected and cannot be examined without correction to clarify the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-9, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Terahara et al (WO 2002/038139 – please note that citations will be referenced to U.S. Patent Publication # 2004/0028724, the national stage of the WIPO document and a certified transition).

Terahara et al. teaches an adhesive pharmaceutical preparation for transdermal absorption of drugs comprising a polymer, drug, penetration enhancers, plasticizers, rubber polymers, releasing paper (for transdermal patch), resins, antioxidants, filler and

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many other components for transdermal patches that are known in the art (Abstract, Page 1, paragraph 7-9, Page 2, paragraph 10-12, 15, 21-22, Page 3, paragraph 23-24, 27-29, 31-32, Page 4, paragraph 34, 41-45, claims 1-8).

Terahara teaches is a specific example of a transdermal adhesive patch for pergolide mesilate (same as pergolide mesylate) that is comprised of Eudragit® (a methacrylate/methacrylic copolymer), acrylate polymer, resin, and alcohol. The composition was made, placed on releasing paper as the adhesive layer, and affixed with a backing (Page 5, Example 5, paragraph 56-57).

The type of metabolites, plasma levels, and AUC ratio of the claims is a limitation is in a patentable sense, but only requires that ability to so perform. As the compositions are nearly identical and the percentages for the pergolide salt are identical, the expected metabolite formation, plasma levels, and AUC ratios would inherently be met.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

11. Claims 1-9, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Arth et al. (U.S. Pat. # 6,461,636).

Arth et al. teaches a composition and transdermal therapeutic system (TTS) for the delivery of pergolide.

The TTS is a transdermal plaster (patches) applied to the skin with an impermeable covering layer, a removable layer, and a matrix containing the active substance or a reservoir of the active substance with a semi permeable membrane. Arth teaches the matrix layer to contain methacrylate copolymer, propylene glycol, and

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pergolide. Table 1 teaches preparations containing propylene glycol, methacrylic and acrylate polymers, and pergolide mesilate at similar percentages to the working example in the instant application (1.47-1.74 verses 0.9%). The pergolide can be a free base, a salt, and the preferred form is pergolide mesylate (Abstract, Col.2, lines 11-34, Col. 4, lines 43-68, Col. 5, lines 1-13, 35-40, Col.6, lines 45-68, Col. 7, Examples 1-3, lines 1-43, claims 1-3).

The type of metabolites, plasma levels, and AUC ratio of the claims is a limitation is in a patentable sense, but only requires that ability to so perform. As the compositions are nearly identical and the percentages for the pergolide salt are identical, the expected metabolite formation, plasma levels, and AUC ratios would inherently be met.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Conclusion

12. Claims 1-12 are rejected.

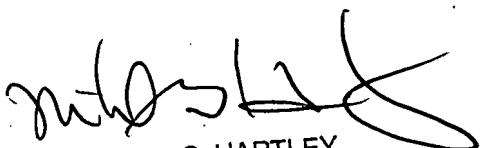
Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER